EXHIBIT A

VIGILANTE FORENSIC

Human Factors | Ergonomics Consulting

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Case Caption:	Pamela Brackin Vs. Medtronic, Inc., et al.
VF Case Number:	18-139
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A. INTRODUCTION

At about 5:30 pm, on January 15, 2016, Bryan Brackin returned home from work and found his wife Pamela unresponsive in a chair. Pamela apparently suffered an episode of severe hypoglycemia which put her in a coma. Pamela died a week later from hypoxic ischemia encephalopathy caused by severe hypoglycemia from an overdose of insulin.

Pamela Brackin was an insulin-dependent diabetic who requires exogenous insulin to regulate the glucose levels in her body since she cannot produce insulin on her own. In August of 2013, Pamela was prescribed a Medtronic Paradigm infusion system to dispense insulin into her body. The system consists of a Medtronic Paradigm 523 Insulin pump and Medtronic QuickSet infusion set. The pump uses a disposable Paradigm reservoir that connects to the infusion set to transfer the insulin into the body. Late in the evening of the day before she was found unconscious, her husband had performed a reservoir fill and assisted in the infusion set change before going to bed. At some point the system malfunctioned causing an unintended and unknown over-infusion of insulin into Pamela's body.

The pump and reservoir were designed and manufactured by Medtronic Inc. The connector cap on the infusion set through which the infusion set connects to the reservoir for delivery of insulin was designed by Medtronic but manufactured by Unomedical a/s who assemble the catheter and connector cap into a completed unit. The infusion set uses a Medtronic propriety P-cap connector to connect the infusion tubing to the reservoir. Medtronic has identified a "temporary blocked vent" hazard created by the design of their P-cap connector. The hazard occurs when liquid gets on the interior side of the P-cap connector's vents. The vents are used to regulate the pressure within the connected reservoir. The presence of liquid on the interior side of the P-cap connector can block the vents preventing the equalization of pressure within the reservoir. If the reservoir's pressure is higher than the atmospheric pressure, its plunger will advance on its own, pumping the insulin uncontrolled through the infusion set and into the patient.

The purpose of my investigation was to determine if:

- Medtronic's failure to conduct an adequate human factors analysis of its products was improper in a manner which caused or contributed to Pamela Brackin's injury and death.
- Medtronic provided adequate instructions and warnings with its Paradigm reservoir and infusion set regarding the hazard associated with the potential blockage of the P-cap connector vent.
- Medtronic's failure to provide adequate instruction and warning regarding the hazard associated with the potential blockage of its P-cap connector vent was improper in a manner which caused or contributed to Pamela Brackin's injury and death.

I have included an updated CV outlining my qualifications and a listing of my testimonies for the past four years within the Appendix section of this report. Vigilante Forensic currently invoices my work associated with this investigation at a rate of $395.00 per hour.

I may use the following materials as exhibits to illustrate my testimony: photos taken of the Paradigm infusion set and reservoir; exemplar Paradigm infusion set, reservoir, and pump; relevant IFU instruction sheets and instructional guides provided by Medtronic and Unomedical; Medtronic online tutorial and videos discussed in the report; examples of warnings used for other types of medical products; the YouTube videos discussed in the report, the example warnings described in Section E-4 of this report, and the references and standards cited within this report.

B. AVAILABLE MATERIAL

- Plaintiff's:
  - Amended Complaint
  - Handwritten notes and timeline
- Medtronic:
  - Urgent Medical Device Safety Notification, dated 6/7/2013
  - Medtronic's recall announcement dated 9/11/2017
  - IFUs for Paradigm reservoir and Infusion set
  - Medtronic Getting Started Guide
  - Tutorial videos for Paradigm pump and infusion set
  - Videos:
    - Create Primefill anomaly
    - Drops of diluent onto membrane test strip
    - Temp Vent Block During Prime
    - Pumpenfehler 1 and 2
    - Sterile Gauze Wipeup drop
- Deposition transcripts and exhibits of:
  - Amichai Vardi, dated 10/14/2015
  - Antatoly Aleksandrovich, dated 5/18/2018
  - Anthony Vicente, dated 5/30/2018
  - Bryan Brackin, dated 3/29/2018
  - John Duarte, dated 5/12/2015
  - Karen B. Fisk, dated 10/14/2015
  - Mark Steven Curtis, dated 5/14/2015
  - Rabi Gharabli, dated 10/10/2015
  - Randy Adair, dated 9/30/2015
- Various medical records

C. PRODUCT DESCRIPTION

Pamela Brackin was using a Medtronic Paradigm insulin delivery system. The Paradigm insulin delivery system consists of a Medtronic Paradigm Real Time Insulin pump (model number MMT-523), disposable Paradigm Reservoirs (model No. MMT-326A), and disposable Medtronic Quick-set infusion sets (model No. MMT-397). Medtronic intended the reservoir and infusion sets to be replaced every two to three days with new ones.

The Paradigm pump is user programmable to deliver insulin into the body at a programed rate. The pump has a user interface with several buttons to setup and control the pump and delivery rate. The user can also administer additional doses (or boluses). The pump possesses a maximum bolus feature which limits the amount of insulin that can be delivered in a single bolus. The factory setting is 10.0 units but is user programmable from 0.0 to 25.0 units. A cavity (i.e., reservoir compartment) is located in the bottom left side of the pump. The Paradigm reservoir is inserted into the compartment. The pump also possesses a slide screw that interfaces with the reservoir to dispense the insulin.

The Paradigm reservoir is a disposable plastic vessel that can hold up to 1.8 ml of insulin. The body of the reservoir is marked in 0.2 ml increments. The reservoir possesses a plunger with a removable push handle. The plunger moves within the plastic body of the reservoir. The top of the reservoir tapers down to a connection point. A rubber septum is crimped down over the top of the reservoir. The user removes the plunger handle before inserting the reservoir into the compartment in the bottom left side of the pump. The pump's slide screw advances forward into the reservoir body and pushes on the bottom side of the reservoir's plunger to move the insulin out of the top of the reservoir and into the infusion set.

The Paradigm reservoir is shipped with a transfer guard attached to the top of it. The transfer guard is used to fill the reservoir from a vial of insulin. The insulin vial is connected to the opposite end of the transfer guard. Once the reservoir is filled, it is removed from the transfer guard.

The infusion set was designed and manufactured by Unomedical to Medtronic's specifications. The infusion set includes a 23 inch long piece of plastic tubing that connects the Paradigm reservoir to the cannula. The cannula is inserted under the user's skin and possess a quick disconnect that attaches to the one end of the tubing. The other end of the tube terminates at a P-cap connector. The P-cap connector connects to the top of the reservoir before it is inserted into the pump body.

The P-cap connector is a proprietary, Medtronic design. Medtronic designed the P-cap connector as part of their effort to make their insulin delivery system waterproof. The P-cap connector possesses four small vents at the top of the connector. The vents are used to equalize the pressure within the reservoir. A membrane is located on the underside of the vents. The membrane consists of two layers. The top/outer layer is made of polytetrafluoroethylene (PTFE) and is used to prevent liquids (e.g., water) from entering the

reservoir (hydrophobic). The inner/lower layer is made of a woven polyester and is used to support the top PTFE layer. The P-cap connector snaps onto the top of the reservoir once the reservoir is filled with insulin.

The Medtronic Paradigm pump is accompanied by a User Guide. The Pump's User Guide is 243 pages long and printed solely in English. The User Guide consists of 15 chapters and an appendix. The chapters include information on preparing your pump for use and programming the pump. Medtronic also provided a 69 page Getting Started guide. The guide provides a 10 section "Step-By-Step Guide" for using the system as well frequently asked questions, training handouts, and an appendix.

The Paradigm reservoir and infusion sets are purchased separately and each includes a fold out, two sided instructional sheet. The reservoir instructional sheet is printed in 21 languages, including English. The reservoir instructional sheet depicts 12 steps for filling the reservoir and attaching it to the infusion set with the P-cap connector. None of the steps are accompanied by textual instructions.

The instructional sheet (i.e., instructions for use or IFU) for the Paradigm infusion set is printed in 21 languages, including English. The infusion set instructional sheet refers the user to the pump and reservoir user guides for installation and priming. The infusion set instructional sheet depicts 10 steps for connecting the infusion set to the pump and cannula quick disconnect (QD) on the body, 4 steps for disconnecting the tubing from the cannula QD, and 3 steps for reconnecting the tubing to the QD. Although the three tasks are labeled, the individual steps are not accompanied by textual instructions. The instructions sheet also presents indications for use, contraindications, warnings, and the warranty in each of the 21 languages.

D. INCIDENT DESCRIPTION

The following facts are derived from the Pleadings, medical records and testimony:

Pamela Brackin was an insulin-dependent diabetic initially diagnosed in the mid-1990's and initially treated with oral insulin before being switched to injections in 1998. In 2009 she came under the care of Dr. Abbas Kitabchi who managed her diabetes until he left the practice in 2012. Pamela's diabetes was poorly controlled and on her last visit with Dr. Kitabchi in February 2012, an insulin pump was recommended. Pamela declined the use of the pump at that time because she had just had a PEG tube placed and did not feel capable of managing both the tube and an insulin pump. From February 2012 until July 2013 Pamela did not see any physician on a regular basis for the management of her diabetes.

In July 2013, apparently at the urging of her daughter Lucie, Pamela came under the care of Rita Goidel, a Nurse Practitioner in Memphis who prescribed an insulin pump for her. Pamela began insulin pump therapy in August 2013 which, according to her husband Bryan Brackin, worked

well for her (BB, 198). Bryan testified that after Pamela began her pump therapy "she was leveled out with the pump . . . [it was] far better than what it had been" (BB, 198).

There is no evidence to suggest that Pamela had any problems with her pump therapy between August 2013 and January 15, 2016 when she was hospitalized. According to Bryan Brackin sometime during the day of January 14, 2016 the pump registered a low reservoir alarm and that evening, shortly before midnight, he filled an insulin reservoir for his Pamela and helped her change the infusion set. (BB, 202). Bryan then went to bed.

Shortly before 5:00 AM the next day, Bryan left for work (BB, 202). Bryan testified that the living room, where his wife usually slept, was dark and that he could not see Pamela but he would not have disturbed her anyway (BB, 204, 205). When Bryan came home from work around 3:00 PM he saw Pamela in the chair and thought she was taking a nap, as she very often did (BB, 205, 206). Assuming that Pamela was asleep, Bryan did not disturb her and left to do an errand and pick up their grandson (BB, 206).

After stopping to pick up his grandson, Bryan returned home at around 5:15 PM. When his grandson could not wake Pamela up, Bryan went over and shook her to try to wake and noticed that her temperature did not feel right and he realized that he "needed to get glucagon in her quick" (BB, 207). Bryan checked Pamela's blood sugar and found that it was "below 20" and gave her glucagon and called 911 (BB, 210). After waiting approximately 5 minutes, Bryan tested Pamela's blood sugar again and it was still reading less than 20 (BB, 210). Bryan also heard an alarm and checked the insulin pump which displayed a "low reservoir" warning (BB, 212).

Bryan then went next door to the house of his neighbor, a retired nurse, and found her standing in the driveway with another friend who was not only also a retired nurse but an insulin pump patient who uses a Medtronic insulin pump similar to the one used by Pamela (BB, 212). Jane Hartley, one of the nurses and the insulin pump user checked the bolus history of the pump and found that no bolus doses had been delivered that day (Affidavit of Jane Hartley).

Paramedics arrived at approximately 6:43 PM and noted that the patient's blood glucose (BG) was less than 20 and that she was unresponsive. The paramedics administered two ampules of D50 and Pamela's BG was noted to rise to 220 but she remained unresponsive (16MUH-00964). Pamela was transported to the Emergency Department at Methodist University Hospital in Memphis.

Shortly after arriving at the hospital, Bryan Brackin returned to his car to retrieve the pump to provide it to the treating physicians in the hope that it could provide information about what had happened to his wife (BB, 213). When Bryan retrieved the pump from his car, the pump was alarming and displayed an electronic screen message "MOTOR ERROR" (BB, 213). The next day Bryan called Medtronic's Help Line and spoke to a representative about the motor error message (BB, 239, 240). This led him to query the history of the pump which he manually recorded as well as photograph some of the screens (BB, 240).

Bryan's recording of his query shows a low reservoir alarm at 3:21 PM on the afternoon of January 14, 2016 and then what appears to have been a reservoir fill at approximately 11:20 PM later that evening with a manual prime of 3.1 units and a basal rate set at 0.5 units/hour. That is followed approximately 13 ½ hours later by a low reservoir alarm at just before 1:00 PM on January 15th. The first low reservoir alarm is followed by another low reservoir alarm a little less than an hour and a half later at 2:17 PM. 3 ½ hours later a "no delivery" alarm is noted and at 7:01 PM an "empty reservoir" alarm is recorded followed less than an hour later by a "motor error" alarm (Brackin Exhibit 3 at 35, 36). In addition, Bryan also retrieved the daily dosing history which showed a total daily dose of 26.825 units delivered on January 14 and 132.7 units on January 15 following the reservoir fill and infusion set change (Brackin Exhibit 22).

E. ANALYSIS

E.1. Hazard identification.

The design of Medtronic's P-cap connector creates the potential hazard of unintended over or under delivery of insulin. The P-cap connector is integrated into the Medtronic Quick-set infusion set tubing during manufacturing (RA, 23). The P-cap connector is used to connect the infusion set to the Paradigm Reservoir. The disposable reservoir is user filled and purchased separately from the infusion set and pump. The reservoir has a plunger that moves within its body to fill and release the insulin. Once filled, the reservoir is placed in the Paradigm pump where the pump's slide screw interacts with the plunger to push insulin from the reservoir, through the infusion set, and into the body at a pre-programmed rate (or additional bolus when needed).

Medtronic's P-cap connector is a propriety design that can only be used with Medtronic Paradigm pumps (RA, 24,34,35). Medtronic designed their P-cap connector in the 1999/2000 time frame (RA, 24). The P-cap connector was designed as part of Medtronic's requirement to make their Paradigm pump waterproof which required them to prevent moisture from getting into the reservoir (RA, 28,44). Prior to the design and use of their P-cap connector, the industry standard connector was a Luer Lock connector (RA, 26). However, the Luer Lock connector was not waterproof (RA, 31,32).

Because the system was waterproof, Medtronic designed the P-cap connector with four vents located at the top of the connector to equalize the atmospheric and internal pressure of the reservoir (RA, 30,53,55). Any pressure differential between the interior of the reservoir and the atmosphere can affect the operation of the system (RA, 44). For example, Randy Adair, the Medtronic designer of the P-cap connector, testified that it is theoretically possible that the plunger could move without input from the user if there is a pressure differential between the atmosphere and the interior of the reservoir (RA, 24,45,46). Randy Adair also testified that if the pressure in the reservoir exceeds the atmospheric pressure, the resulting forces can cause the reservoirs' plunger to be driven inward thus delivering unwanted insulin (RA, 109,110).

To make the vents waterproof, Medtronic added a two layer membrane under the vents. The top, outer layer was a PTFE, water proof (hydrophobic) membrane (RA, 42). The bottom, inner layer consisted of a woven polyester used to support the PTFE water proof layer. The P-cap connector was the first connector system designed with built-in venting (RA, 31). The Luer Lock connector did not have or need any vents or membranes because it was not waterproof (RA, 34).

To use the Paradigm insulin infusion system, the user must fill the reservoir with insulin and then manually prime the insulin through the infusion set tubing. The reservoirs are shipped with transfer guards attached to them. The transfer guard is a two sided device with needles on both ends to puncture the septums of the insulin vial and reservoir. Once the user attaches the insulin to the opposite side of the transfer guard, they have to hold the reservoir upright and the insulin vial upside down. In this orientation, the user pushes the reservoir plunger in to introduce air into the insulin vial. The user then retracts the plunger, pulling the insulin into the reservoir. The effect of pushing air into the insulin vial increases the pressure within the insulin vial (RA, 56). Once the reservoir is filled to the determined level, it is removed from the transfer guard and inserted into the pump cavity. However, if the reservoir is removed while the insulin vial is inverted, insulin can squirt out due to the increased pressure in the vial and contaminate the top of the reservoir.

The next step in the process is for the user to attach the P-cap connector to the top of the reservoir. If the top of the reservoir is contaminated with insulin from the transfer process, or any other liquid, it can get on the bottom/inner layer of the P-cap membrane. If liquid gets on the bottom of the membrane, it can block the flow of air through the vents in the P-cap connector. If the vents are blocked it can prevent the equalization of pressure within the reservoir to the atmospheric pressure.

After connecting the P-cap connector to the reservoir, and pushing any air bubbles out of the reservoir and into the infusion set tubing, the user places the reservoir in the pump to manually prime the system. Priming is done by pressing a button on the pump to move the pump slide screw forward. The user is instructed to hold the button until they see insulin dripping from the end of the infusion set QD. Once they see insulin dripping from the tubing QD, the user is instructed to connect the tubing QD to the cannula QD and then prime the cannula to finish the process.

However, Randy Adair testified that the priming process can increase pressure in the reservoir (RA, 56,111). If the P-cap membrane is contaminated with liquid and the vents are blocked, the increased pressure in the reservoir will not vent to the atmosphere and the plunger can begin to move in on its own (RA, 111). The result is insulin dripping from the end of the QD tubing before the slide screw contacts the reservoir plunger. This phenomena can fool the user into thinking the slide screw has properly moved into the plunger and end the priming process before the slide screw actually contacts the reservoir plunger. Due to the pressure in the reservoir, the plunger can continue to move on its own, delivering unwanted insulin into the

body without the user or pump knowing. The over delivery of insulin puts the user at risk of serious injury and potentially death.

The unintended delivery of insulin resulting from the blockage of the P-cap connector vents created a hazard to users of the Paradigm infusion set and reservoir.

E.2. Medtronic failed to conduct a proper human factors analysis.

Medtronic as the designer of the infusion set and reservoir had a responsibility to identify the hazard associated with the reasonably foreseeable use and misuse of their products (1-5). Even though Randy Adair testified that he knew from his engineering background that the inability to equalize the pressure within the reservoir can result in the unintended movement of the plunger and unwanted delivery of insulin, Medtronic did not identify the hazard until after it released its products into the market place. In fact, it was not until 2013 that Medtronic identified the hazard and how and why it occurs. Although Medtronic did not recognize the risk until the 2013 time frame, the hazard was foreseeable at the time the P-cap connector was designed and introduced into the market place in the 1999/2000 time frame through adequate risk analysis and typical human factors analysis.

Risk (hazard) analysis is a formal process of assessing the risks and hazards associated with the foreseeable uses and misuses of a product (1-3). Risk analysis and hazard identification are critical steps to ensure the safety of product users and those exposed to the potential consequences of the hazard (1-3). Risk analysis can take many different forms and includes identifying human factors such as (1-3):

- Who will use the product and where;
- How the user will interact with and/or use the product;
- The mistakes and errors that user can make when using the product; and
- The instructions and warnings needed to use the product safely.

Human factors is the scientific discipline associated with designing for human use. Human factors in product design focuses on the product from the point of view of the user to determine how different design features and/or information will affect how the user interacts with or uses a product. Human factors analysis is used to identify incompatible tasks, tasks demands that are likely to cause error, user expectancies and tendencies, and how to design the product to reduce user errors and ensure user efficiency, comfort, and safety.

Human factors is relied upon in the design of products, including medical devices, particularly as product systems have become more complicated and complex (1-4). Similar to risk analysis, human factors must be integrated into the design of the system from conception through the products life cycle (1-4). For example, within the "Product Safety Management" chapter of the *Accident Prevention Manual for Business and Industry: Administration and Programs* (APM), the National Safety Council (NSC) notes (2):

> The PSM [product safety management] program auditor must determine if human factors have been considered in product designs. (See Chapter 13, Ergonomics Programs, in this volume.) Some of these human factors include the physical, educational, and mental limitations of the people who will use the products. The program auditor also should determine whether the company has weighed the possibility that customers might use the product in ways other than it was designed to be used but that might be considered reasonable.

The FDA also recommends that medical device designers and manufacturers incorporate human factors into their design process (4). For example, in 2000 the FDA published their *Guidance for Industry and FDA Reviewers on Medical Device Use-- Safety: Incorporating Human Factors Engineering into Risk Management; Availability* in the Federal Register (4). The FDA provides the following summary for the use and intention of recommending the integration of human factors analysis into the design of medical devices (4):

> This guidance describes how to incorporate human factors techniques and theory into risk management during medical device design and development. The guidance is intended to assist reviewers of premarket device submissions, design control documentation, and manufacturers that develop devices. The guidance is necessary to decrease problems with the use of medical devices that impact safety and effectiveness, and help ensure safer and more effective devices.

Risk and human factors analysis

Design analysis

Contrary to industry practices, guidelines, and standards, Medtronic failed to incorporate an adequate hazard analysis or human factors analysis into the design of its infusion set and reservoir (1-5). For example, Randy Adair testified that when he was designing the P-cap connector:

- He was not involved in any risk analysis for the infusion set used in the Paradigm infusion system (RA, 92).
- He was not responsible for identifying any potential risks associated with his design of the P-cap connector (RA, 122,123).
- He never had any discussion with anyone who was responsible for identifying any potential risks associated with his design of the P-cap connector (RA, 122).
- He did not do any human factors testing on the design of the P-cap connector (RA, 71).
- He is not aware of any human factors testing done on the P-cap connector (RA, 71).

To make matters worse, Randy Adair never considered how the P-cap connector that he was designing would be used with the infusion set or how it would be used by the patient. For example, Randy Adair testified:

- During his design of P-cap connector he never filled an insulin reservoir or primed the infusion set (RA, 98).
- When designing the P-cap connector he never actually went through the priming and filling process (RA, 98).
- He is not sure if he ever primed an insulin pump before (RA, 90).
- He is not even familiar with the Paradigm Quick-Set Infusion set (RA, 121,122).

As a result of Randy Adair's failure to understand or attempt to identify how the P-cap he was designing would be used with the infusion system:

- He never considered that insulin could get on inside of P-cap connector (RA, 113).
- He never considered that insulin could spill on top of the reservoir and then be transferred to inside of the P-cap connector (RA, 114).
- He never personally gave any consideration to the effect of insulin spillage on the operation of the P-cap connector (RA, 112,113).
- He never performed any occlusion testing on P-cap connector (RA, 90,91).
- He did not test the effects of insulin on the underside of the P-cap connector (RA, 58).
- He did not consider that increase pressure in the reservoir occurs due to the priming process when he designed the P-cap vents (RA, 56).

Randy Adair also testified that Medtronic never considered the effect of getting insulin on the P-cap connector. For example, Randy Adair testified:

- He is unaware of any consideration they gave to the effect of insulin spillage on the operation of the P-cap infusion set (RA, 112,113).
- The potential for insulin to get on inside of the P-cap was never brought up for discussion (RA, 113,114).

Usability studies

Susan McConnell-Montalvo, who led Medtronic's design team for the disposables project, testified about two "Usability Studies" that were conducted with the paradigm system IFUs in the early 2000s. McConnell-Montalvo testified that these usability studies were conducted to assess the effectiveness of the IFU and to determine if the users could properly perform the reservoir filling task based upon the IFU used in the studies (SMM, 177,182). However, the human factors studies were conducted with a different IFU than were shipped with the products that were used by Pamela. Brackin. The IFU used in the human factors studies depicted the insulin vial sitting (upright) on a table with the reservoir held above it when the reservoir was filled and disconnected from the transfer guard (SMM, 176-178). The IFU provided to Brackin does not depict the insulin vial sitting upright on a table during any step of the reservoir filling task.

McConnell-Montalvo testified that when they designed and developed the Paradigm pump system they were aware that if the reservoir was removed from the transfer guard when it was held below the insulin vial that insulin could squirt out and that is why the IFUs used in the usability studies depicted the insulin vial sitting upright on the table (SMM, 178,179). Although Medtronic was aware of this potential, it changed the IFU after the human factors studies (SMM, 189,192,193). There has been no information provided to suggest that Medtronic conducted any additional human factors studies on the version of the IFU shipped with the reservoir products used by Pamela Brackin or that Medtronic validated the adequacy of the IFUs provide to Pamela Brackin when she initiated pump therapy. Putting aside the adequacy of the IFUs, Medtronic's usability studies failed to uncover the hazard inherent in the design of the P-cap and how foreseeable user misuse (i.e. removing the reservoir while it is below the insulin vial) could result in a failure of the connector cap and potentially result in an overdose.

Task analysis

There are multiple different tools and testing techniques other than usability assessments that human factors professionals utilize to assess the needs of users and the design of products including task analysis (1,3). However, at the heart of human factors analysis is task analysis (1,3). Task analysis is used to understand how people will use a product, the steps necessary to complete each task, and the tools and information necessary to safely complete each task (1,3). Task analysis starts with outlining the tasks necessary to accomplish a goal (e.g., prime the infusion set). Each task is then broken into the individual steps needed to accomplish the individual tasks (e.g., connect reservoir to infusion set) (1,3). Each step is analyzed to determine such things as the stimuli that initiates the step; the decisions needed to perform the step; the actions required to complete the step; the information necessary to complete the step; the potential sources of error and stress when completing each step; and the potential hazards associated with incorrectly performing the step (1,3). Task analysis is also used to identify the difficulty, error likelihood, and criticality for each step of the task.

Basic human factors principles and known user tendencies and expectations are considered in the analysis of each step. Basic human factors principles, tendencies, and expectations that should be assessed during the task analysis include (1,3,5-7):

- People prefer to use their dominant hand for tasks that require fine motor skills;
- Users prefer postures and positions that are comfortable and require the least amount of stress and/or force;
- People prefer to take the path of least resistance;
- People assume products are safe, do not look for unknown hazards, and therefore do not take proactive steps to avoid them;
- People expect objects to operate and move consistent with normal conventions (e.g., turn control clockwise to increase or turn on, turn counterclockwise to turn off or disengage);

- People lack knowledge about and experience with technological features of many products (e.g., equalization of atmospheric pressure and its effect on vials);
- At times people are likely to forget, become distracted, or in a hurry; and
- People need adequate warnings and instructions to recognize and avoid non-open and obvious hazards.

To compensate for these human factors, product designers and manufacturers should (1-3,5):

- Consider the user's preferred hand when tasked with performing fine motor skills (e.g., manipulating small vials with their fingers);
- Design the tasks to eliminate undo muscle strain and stress;
- Simplify tasks and keep the number of steps to the required minimum;
- Ensure tasks, controls, and products operate consistent with normal convention and stereotypes;
- Design the system to preclude misuse (i.e., cannot incorrectly complete task), ensure task continuity and pace (cannot perform task steps out of sequence), minimize the effects of error, and/or attract the user's attention to critical steps;
- Eliminate the hazard from the design of the system and if that is not possible include necessary safe guards to prevent injury; and
- Provide adequate warning and instruction to alert users to any residual hazard potential associated with the design of the system.

With respect to the vent blockage hazard, task analysis would have revealed the potential of users to get liquid, including insulin, on the underside of the P-cap connector. For example, Medtronic provides IFU (information for use) instruction sheets with its infusion set and reservoir. The IFUs provided with the products used by Pamela Brackin were (2014) revisions of the original IFUs that Medtronic used when they released the product. Although content and format of the IFUs changed over time, an adequate task analysis of both IFUs reveal the potential for users to get liquid on the underside of the P-cap connector.

Original reservoir IFU

The original reservoir IFU provides 10 steps for filling the reservoir and connecting it to the infusion set tubing via the P-cap connector. Contrary to basic human factors principles and guidelines for product design, a task analysis of the original reservoir IFU reveals that users have to:

1. Swap the reservoir from their right hand on three occasions:
    a. Step 1-4 is done with the user holding the reservoir in their right hand
    b. Step 5 is done with the user holding the reservoir in their left hand;
    c. Step 6 is done with the user holding the reservoir in their right hand; and
    d. Steps 7-9 is done with the user holding the reservoir in their left hand.
2. The user has to flip the orientation of the reservoir twice:

   a. The reservoir starts inverted and then is flipped up right to fill.
   b. Step 6 requires the user to invert the reservoir to disconnect it from the insulin vial.
   c. Step 7 requires the user to flip the reservoir up right to connect the P-cap connector.
3. Assume a stressful shoulder posture:
   a. As depicted in the IFU, step 7 requires the user to raise their right shoulder and rotate it forward to connect the P-cap connector to the reservoir.
4. Assume a posture contrary to normal convention:
   a. Steps 6 and 7 require the user to hold their dominant (i.e., right) hand over their non-dominant hand;
      i. People normally grasp with their non-dominant hand over their dominant hand (e.g. opening a screw top bottle, the bottle is held in the right hand and the cap in the left hand with the bottle below the cap).
5. Initiate a complex movement:
   a. In step 7 the right wrist has to flex down and supinate to connect the P-cap to the reservoir (being held in the left hand) because the right arm is held over the reservoir.

<u>2014 reservoir IFU</u>

The 2014 reservoir IFU provides 12 steps for filling the reservoir and connecting it to the infusion set tubing via the P-cap connector. Contrary to basic human factors principles and guidelines for product design, a task analysis of the reservoir IFU reveals that users have to:

1. Swap the reservoir to their right hand on four occasions:
   a. Step 2 is done with the user holding the reservoir in their left hand;
   b. Steps 3 to 5 are done with the user holding the reservoir in their right hand;
   c. Steps 6 to 8 are done with the user holding the reservoir in their left hand;
   d. Step 9 is done with the user holding the reservoir in their right hand; and
   e. Steps 10 and 11 are done with the user holding the reservoir in their left hand.
2. The user has to flip the orientation of the reservoir three times:
   a. The reservoir starts up right and then is inverted to attach to the insulin vial in steps 3 and 4.
   b. Steps 5 to 8 require the user to flip the reservoir back up to fill it and remove any bubbles.
   c. Step 9 requires the user to invert the reservoir to remove it from the transfer guard and insulin vial.
   d. Steps 10 requires the user to flip the reservoir back up to attach the P-cap connector.
3. Assume a stressful wrist posture:
   a. The first half of step 5 requires the user to hold the reservoir and vial in their right hand between their index and middle finger with the insulin vial above the

reservoir and their right thumb on the top of the plunger and pressing it fulling into the reservoir.

   b. As depicted in the IFU, the first half of step 5 require the user to contort their right wrist in an awkward and uncomfortable position (i.e., a combination of flexion and radial deviation to position the thumb on the top of the plunger).

4. Assume a stressful shoulder posture:
   a. As depicted in the IFU, step 10 requires the user to raise their right shoulder and rotate it forward to connect the P-cap connector to the reservoir.
5. Assume a posture contrary to normal convention:
   a. Steps 9 and 10 require the user to hold their dominant (i.e., right) hand over their non-dominant hand;
      i. People normally grasp with their non-dominant hand over their dominant hand (e.g. opening a screw top bottle, the bottle is held in the right hand and the cap in the left hand with the bottle below the cap).
      ii. Step 11 depicts a more natural posture where the reservoir is held at a slight angle rather than perpendicular when removing the plunger.
6. Initiate a complex movement:
   a. In step 10 the right wrist has to flex down and supinate to connect the P-cap to the reservoir (being held in the left hand) because the right arm is held over the reservoir.

A proper human factors analysis of either the original or 2014 IFU would have also revealed that the natural way (consistent with movement expectancy's, least stressful position, quickest, and the least steps) to perform the same task involves holding the reservoir in the dominant (e.g., right) hand at a slight angle during each step of the process. Holding the reservoir in the user's dominant hand has the following advantages for the user:

1. Reduces the number of steps because the user only has to swap hands and flipped the reservoir once (when attaching p-cap to the filled reservoir).
2. The user does not have to flex and radial deviate the wrist in step 5 of the 2014 IFU.
3. The user does not have to elevate their shoulder in step 7 or the original IFU and step 10 of the 2014 IFU.
4. The user's dominant hand stays naturally below the support hand in all tasks consistent with normal tendencies and typical behavior.
5. The user's wrists stay neutral in steps 6 and 7 of the original IFU and step 10 of the 2014 IFU and only requires a simple rotation of the right wrist.

Video analyses

The natural way to fill the reservoir and connect the P-cap is depicted in Medtronic's "Create PrimeFill Anomaly" video. In the video, the user holds the reservoir, transfer guard, insulin vial combination at a slight angle with the reservoir below the insulin vial.

The natural way to fill the reservoir and connect the P-cap is also depicted in videos of users. For example, I conducted an internet search for YouTube videos related to people using and instructing others on how to refill and connect a Mini-med/Medtronic infusion set and reservoir using their proprietary P-cap connector. I was able find 13 YouTube videos depicting non-medical professionals or Mini-med/Medtronic sponsored product users (see Appendix). Of the 13 videos, seven depicted the user removing the reservoir from the transfer guard with the insulin vial still connected to the transfer guard and held above the reservoir. In one of these seven videos the user instructs the viewer that she is going to depict the "proper" way of filling the reservoir and connecting the infusion set.

In two of the videos the user held the insulin vial, transfer guard and reservoir sideways. In one of the videos the user removes the insulin vial from the transfer guard first. In this video the user alerts the viewer of the need to flip the unit upside down before disconnecting the insulin vial from the transfer guard (with reservoir still attached) but then subsequently turns the set sideways before removing the insulin vial. In the second video, the user removed the reservoir from the transfer guard first.

In four of the videos, the user holds the reservoir above the insulin vial before removing it from the transfer guard. In one of the videos, the user places the insulin vial upright on the table and then disconnects the reservoir from the transfer guard. Within this video the user explains why it is necessary to disconnect the reservoir in this fashion and instructs the viewer to ensure the top of the reservoir is dry before attaching the p-cap connector. Another video depicts a child who fills his reservoir and then hands the unit it to his mother to remove the air bubbles. After checking the reservoir for air bubbles, the mother hands the unit back to the child with the insulin vial on the bottom. The child takes the unit and pulls the reservoir off the transfer guard without seeming to ensure or care that the reservoir was held above the insulin vial. The third video is titled "How to change your infusion set for your Medtronic pump (the poor and unsafe way lol...)."

Consistent with an adequate task analysis for filling the reservoir, the YouTube videos support the conclusion that given the sequence of the earlier tasks, the natural, and therefore foreseeable, manner in which to remove the reservoir from the transfer guard is the with the reservoir held below the insulin vial.

Hazard identification

Based upon the task analysis it was also evident that the natural manner in which to remove the reservoir from the transfer guard can result in insulin dripping from the insulin vial due to its position above the reservoir and the increased pressure added to the vial during the insulin transfer step. For example, Mark Curtis, Medtronic certified validation engineer, "accidentally" recreated the problem when testing the infusion system to determine the root cause of the reported anomaly (MSC, 24,159). Mark Curtis testified that when they were conducting their tests he noticed a drop of diluent (green solution with similar consistency of insulin used for testing) on the reservoir top (MSC, 159-160,162). Mark Curtis testified that he was shown how

to fill the reservoir, had done it on one to two dozen prior occasions, had seen other people do it, knew how to do it correctly, and was trying to do it correctly (MSC, 160,161,163-166). Even though he was trained, had seen others compete the steps, and had done it himself, Mark Curtis removed the reservoir (step 6 in the reservoir IFU) from the transfer guard with the insulin above the reservoir (MSC, 167,168). The naturalness of Curtis's action is also reflected in the fact that he did not understand how the green dot of dilute ended up on top of the reservoir at first and had to think back to what he might have done differently before figuring out he had the reservoir under the insulin vial when he removed it from the transfer guard (MSC, 160,161,167). The YouTube videos are also consistent with Curtis's actions and testimony and indicate that many users are not aware of the proper way to fill the reservoir and are at risk of blocking the p-cap vents due to insulin contaminating the top of the reservoir when it is removed from the transfer guard.

The amount of insulin that may drop from the insulin vial is related to the amount of insulin left in the vial, the amount of air the user pumped into the vial in step 2 of the reservoir IFU, and the angle at which the insulin vial is held in relation to the reservoir when the reservoir is removed. Therefore, the insulin may only drip out and onto the top of the reservoir as Mark Curtis described as opposed to squiring out as depicted in Medtronic's "Create PrimeFill Anomaly" video. Insulin is also clear and is more difficult to detect on the top of the reservoir compared to the green diluent. For example, Mark Curtis testified that had he been using insulin it would have been harder to see on the reservoir (MSC, 162,163). A small amount of clear liquid on the top of the reservoir is likely to go unnoticed by the user when connecting the P-cap to the reservoir without adequate warning that the phenomena could occur.

Knowing that the interior of the P-cap connector could get wet, Medtronic should have determined what the potential consequence of the occurrence. For example, Medtronic was aware that silicon oil on the P-cap vents could block the movement of air and cause a similar issue (AmV, 155). In fact, Medtronic issued a recall in June 2009 due to a manufacturing defect in their "Lot 8" Quick Set infusion sets (AmV, 154). The Lot 8 recall preceded Pam Brackin's injury by more than 4 years.

Had Medtronic performed an adequate human factors analysis of its reservoir, infusion set, and P-cap connector it would have identified the potential for users to remove the reservoir while it was upright under the insulin vial, insulin to contaminate the P-cap membrane, and the hazard created by the blockage of the P-cap connector vents.

Medtronic's failure to conduct an adequate human factors analysis resulted in its failure to identify the potential for liquids, including insulin, to contaminate the underside of the P-cap connector, the blockage of the vents, and the unintended and unwanted over delivery of insulin into the patient hazard.

Medtronic's failure to conduct an adequate human factors analysis of its reservoir, infusion set, and P-cap connector resulted in its failure to identify the hazard associated with the potential blockage of the P-cap vents prior to releasing the product for sale.

Medtronic's failure to conduct an adequate human factors analysis was improper and unreasonably dangerous and created an unreasonably dangerous condition that caused or contributed to Pamela Brackin's injury and death.

E.3. Medtronic failed to provide adequate instruction and warning.

Product warnings.

Instructions inform a user how to use the product properly and effectively. Warnings alert and inform the user of the hazards associated with the foreseeable use and misuse of the product, how to avoid the hazard, and the consequences for failing to avoid the hazard (1-3,5). Product warnings are used when (1-3,5):

1. A significant hazard exists.
2. The hazard, consequences, and appropriate safe modes of behavior are not known by the people exposed to the hazard.
3. The hazards are not open and obvious; that is, the appearance and function of the environment or product do not communicate them.
4. A reminder is needed to assure awareness of the hazard at the proper time.

Warnings are a means of delegating the responsibility for the product's safety to the user in situations where hazards cannot be designed out or solely guarded (1-3,5). For this reason warnings need to be effective in motivating the user to act and behave in a safe fashion (1-3,5). The effective communication of warnings is also necessary so the user can make an informed decision with regard to the product's use and the risks associated with the product's use and reasonably foreseeable misuse (1-3,5).

To be effective, instructions and warnings need to be specific, explicit, and understandable to the user (1-3,5,8,9). Explicitness refers to the complete and precise presentation of information so that the user does not have to infer a meaning or consequence (8,9). Specific and explicit information is necessary so that product users can identify the specific steps involved in proper use of the product and the specific hazard(s) associated with the use of the product; appreciate the consequences of failing to heed the instruction or warning; understand what is needed to complete the instruction or avoid the hazard; and are motivated to comply with the instruction or warning (1-3,8,9). Research has shown that explicit information leads to (1,8,9):

- Increased memory and understanding;
- Better understanding of what should or should not be done;
- Greater compliance and intent to comply;
- The belief that the manufacturer is concerned with user safety; and
- A higher level of perceived danger and injury severity associated with a hazard.

In comparison, instructions and warnings that are incomplete or not explicit and specific create the potential for the user to interpret the information differently than what the designer intended. Without specific and explicit instruction and warning the user will not have all of the information they need to understand the intention of the designer, identify the associated hazard, properly complete the task or avoid the hazard, and/or understand the consequences of their actions (1,8,9).

Failure to provide any warning.

Bryan Brackin testified that he attended pump training with Pamela (BB, 162-165,262). Bryan testified that during their pump training they were given the Medtronic Getting Started guide by the pump trainer, Kristin Bettis (BB, 163,164,). Bryan also testified that:

- The Getting Started guide was the only instructions or manual that Bettis used during the training (BB, 170).
- Bettis had told them to use the Getting Started guide and told them it was the only book they will need and "it's all right here." (BB, 170,260,262).
- Bettis went through the Getting Started guide and highlighted important information for them (BB, 163,170,261,262).
- They never looked at the pump User Guide or the IFUs that came with the reservoirs or infusion sets because they relied solely on the Getting Started guide as per Bettis' instruction (BB, 171,172,261).

Bryan also testified that he was the one who usually changed Pamela's infusion set and would fill the reservoir when needed and that Pamela never did it herself (BB, 174). Bryan also testified that he would get the Getting Started guide when he filled the reservoir and change the infusion set the first five or six times or so and that he did not need to review it after that (BB, 176).

Pages 57 to 60 of the Getting Started guide provide instructions for "Changing the Quickset Infusion Set Using a Reveal Insulin Pump." The instructions include how "To Fill the Reservoir." The reservoir filling instructions consists of 8 steps. Each step includes both a pictogram and a text description. Step 1 starts with removing the reservoir and transfer guard from the packaging. Step 8 ends with flipping the vial over so that the reservoir is on top and then removing the reservoir from the transfer guard.

The reservoir filling instructions are followed by the "To Connect the Tubing" instructions. The tubing connection instructions consists of three steps each presenting a pictograph and text. Step 1 starts with removing the infusion set from the packaging and connecting the P-cap to the filled reservoir. Step 3 ends with removing the plunger from the reservoir.

The tube connection instructions are followed by the "To Fill the Tubing" instructions which consists of 6 steps. The first step starts with rewinding the pump screw and inserting the filled and P-cap connected reservoir into the pump. The process ends with the tubing filled and

insulin dripping from the end of the Quickset needle and ready to insert into the Quickset infusion set. The Quickset is the attached to the body and the infusion set tubing is then attached to it.

Although the potential for users to get insulin on the underside of the P-cap connector and the hazard it created was foreseeable to Medtronic, Medtronic failed to provide any warning anywhere within the "Changing the Quickset Infusion set Using a Reveal Insulin Pump." instructions within its Getting Started guide. Medtronic also failed to specifically and explicitly alert or inform users of:

- The importance of ensuring the reservoir is above the insulin vial when removing it from the transfer guard;
- The potential to get insulin on the top of the reservoir;
- The need to prevent insulin or other liquids from getting on the top of the reservoir or the underside of the P-cap;
- The hazard associated with getting insulin or any liquid on the underside of the P-cap connector;
- The need to ensure the top of the reservoir and underside of the P-cap are dry before connecting the two;
- The need to check to ensure the pump's slide screw is in contact with the reservoir plunger while priming; or
- The consequences of a blockage of the P-cap connector vents due to insulin or other liquids contaminating the underside of it.

Medtronic failed to provide adequate instructions and warning in its Getting Started guide regarding how to properly and safely fill the reservoir and connect it to the P-cap and the potential of experiencing a P-cap vent block hazard. It was critical for Medtronic to provide adequate instructions and warnings in its Getting Started guide considering the natural tendencies (i.e., holding the insulin vial over the reservoir when disconnecting them) associated with the task and the potential for insulin to contaminate the top of the reservoir and transfer to the underside of the P-cap. It was also critical for Medtronic to provide adequate instructions and warnings in its Getting Started guide given the fact its pump trainers were instructing people to rely on.

Medtronic's failure to provide adequate instructions and warning in its Getting Started guide regarding how to properly and safely fill the reservoir and connect it to the P-cap and the potential of experiencing a P-cap vent block hazard deprived Pamela and Bryan Brackin of critical safety information they needed to safely use the infusion set and reservoir.

Medtronic's failure to provide adequate instruction and warning is also evident in the number of complaint calls they received related to what Medtronic termed their "Prime Fill Anomaly." For example from 2011 to 2013, Medtronic averaged about 90 cases a year where the user complained of the anomaly occurring. In 2012, Medtronic was alerted to two cases in Europe

were "insulin dripping out prior to plunger touching the stopper" was noted. From 2011 to 2013, Medtronic was aware of five reported cases of low blood glucose, including the death of one user who had been using the Paradigm system for 8-9 years, associated with the anomaly. Unomedical reported receiving 257 complaints related to the uncontrolled flow of insulin in 2013 alone (Gharbil – 13).

Medtronic's failure to provide adequate instructions and warning was improper and unreasonably dangerous, rendered their Paradigm reservoir and infusion set defective and unreasonably dangerous, and caused Pamela Brackin's injury and death.

E.4. Adequate instruction and warning.

If Medtronic chose not to design out the hazard associated with the potential blockage of the P-cap vents, it should have ensured that adequate instruction and warning were provided with its infusion set and reservoir (1-3,5,8-11).

The instructions should have conspicuously and explicitly instructed the user on the proper orientation and position of the reservoir when removing it from the transfer guard (1-3,5, 8-11). The warning should have alerted the user to the potential hazard associated with any liquid contaminating the P-cap connector, the need to ensure the top of the reservoir and P-cap connector were dry before connecting them, to dispose of the infusion set if liquid got on the P-cap connector, and the consequences of failing to properly complete the steps (i.e., over or under infusion of insulin). For example, Medtronic and Unmedical should have ensured the Getting Started guide highlighted the need to flip the unit over and ensure the reservoir was above the insulin vial before removing it from the transfer guide. An intervening pictograph (e.g., 8a) of the "To Fill the Reservoir" instructions should have been provided showing the reservoir-transfer guard-insulin vial being inverted as depicted in Figure 1. The pictograph should have included conspicuous arrows to indicate and emphasis that the reservoir was flipped over. For example, Amichai Vardi, Medtronic's prior director of qualify, testified that an arrow is used to emphasize the flipping of the unit (AmV, 45,46,268).

Figure 1. Pictograph for step 6a.

In addition, step 1 of the "To Connect the Tubing" instructions should have been expanded to include a 1a: check top of reservoir before connecting to P-cap. Step 1a should have included a pictograph such as depicted in Figure 2.

Figure 2. Pictograph for step 7a.

A warning should have accompanied step 1a of the "To Connect the Tubing" instructions which stated (11):

Warning.
Ensure the reservoir top and tubing connector are clean and dry.
Liquid can block the vents on the tubing connector causing under or over insulin delivery.
Under or over delivery of insulin can result in severe injury or death.
If the connector gets wet, throw infusion set and reservoir away and use new ones.

The warning should have been formatted consistent with the ANSI Z535.6 (2011) standard for product safety information presented in product manuals and instructions (11).

In conjunction with conspicuous and explicit warning and instructions within its Getting Started guide, Medtronic should have ensured that patients were warned of the potential hazard and how to avoid it during their CDE training and within their online tutorials. Medtronic should have also ensured its CDE trainers and treating physicians were aware of the hazard and were personally alerting their students and patients to the hazard and how to avoid it.

It would have been reasonable for Medtronic to provide adequate instructions and warning within its Getting Started guide. The costs in terms of money, effort, and time to do so would have been minimal and insignificant.

Had Medtronic provided adequate instruction and warning within its Getting Started guide, it would have ensured that Pamela and Bryan Brackin were provided with the information they needed to recognize the proper way to remove the reservoir from the transfer guard and the hazard associated with getting any liquid on the inside of the P-cap and avoid injury.

F. FINDINGS

Within the bounds of reasonable scientific probability, and subject to change if additional information becomes available, it is my professional opinion that:

1. The unintended delivery of insulin resulting from the blockage of the P-cap connector vents created a hazard to users of the Paradigm infusion set and reservoir.
2. Had Medtronic performed an adequate human factors analysis of its reservoir, infusion set, and P-cap connector it would have identified the potential for users to remove the reservoir while it was upright under the insulin vial, insulin to contaminate the P-cap membrane, and the hazard created by the blockage of the P-cap connector vents.
3. Medtronic's failure to conduct an adequate human factors analysis resulted in its failure to identify the potential for liquids, including insulin, to contaminate the underside of the P-cap connector, the blockage of the vents, and the unintended and unwanted over delivery of insulin into the patient hazard.

4. Medtronic's failure to conduct an adequate human factors analysis of its reservoir, infusion set, and P-cap connector resulted in its failure to identify the hazard associated with the potential blockage of the P-cap vents prior to releasing the product for sale.
5. Medtronic's failure to conduct an adequate human factors analysis was improper and unreasonably dangerous and created an unreasonably dangerous condition that caused or contributed to Pamela Brackin's injury and death.
6. Medtronic failed to provide adequate instructions and warning in its Getting Started guide regarding how to properly and safely fill the reservoir and connect it to the P-cap and the potential of experiencing a P-cap vent block hazard.
7. Medtronic's failure to provide adequate instructions and warning in its Getting Started guide regarding how to properly and safely fill the reservoir and connect it to the P-cap and the potential of experiencing a P-cap vent block hazard deprived Pamela and Bryan Brackin of critical safety information they needed to safely use the infusion set and reservoir.
8. Medtronic's failure to provide adequate instructions and warning was improper and unreasonably dangerous, rendered their Paradigm reservoir and infusion set defective and unreasonably dangerous, and caused Pamela Brackin's injury and death.
9. If Medtronic chose not to design out the hazard associated with the potential blockage of the P-cap vents, it should have ensured that adequate instruction and warning were provided with its infusion set and reservoir.
10. It would have been reasonable for Medtronic to provide adequate instructions and warning within its Getting Started guide. The costs in terms of money, effort, and time to do so would have been minimal and insignificant.
11. Had Medtronic provided adequate instruction and warning within its Getting Started guide, it would have ensured that Pamela and Bryan Brackin were provided with the information they needed to recognize the proper way to remove the reservoir from the transfer guard and the hazard associated with getting any liquid on the inside of the P-cap and avoid injury.

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11. ANSI (2011). Z535.6: American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.

H. APPENDIX

YouTube Videos

Reservoir on Bottom:

https://youtu.be/1P_Ct6cAHpc
How I do an Insulin Infusion Set Change with Medtronic Minimed Pump and Mio Infusion Set
SuperGadgetGuy
Published 1/10/2014

https://www.youtube.com/watch?v=yh25v5IpPew
How to change infusion site for MINIMED PARADIGM insulin pump
pbandj64
Published on 4/1/2012

https://www.youtube.com/watch?v=kThQN8KwdvE
Medtronic Minimed Infusion Set Change
The Diabetic Diva
Published 7/24/2014

https://www.youtube.com/watch?v=Px-L2Q1fYEY
Medtronic Paradigm insulin pump: changing the site
Courtney McAlexander
Published 3/17/2010

https://www.youtube.com/watch?v=w8-U9eJKDqA
Insulin Pump Teaching
Cortney McKinney
Published 4/8/2013

- States she is going to show us how to do it correctly

https://www.youtube.com/watch?v=-CfqDezGJF4
T1d from a 6yr old- insulin pump site change
Tim T1D
Published 4/26/2016

https://vimeo.com/3448855
Minimed Paradigm 522 Infusion Set Change Tutorial
Gina Capone
7 years ago – more

Sideways:

https://www.youtube.com/watch?v=7ilyA9QWopA
Medtronic MiniMed 640G insulin pump - Reservoir filling & Infusion set changing
Medtronic Diabetes Europe, Middle East, Africa
(https://www.youtube.com/user/MedtronicDiabetesEU)
Published 8/11/2015

- Reservoir disconnected first

https://www.youtube.com/watch?v=9FCnFO5Wm0w
Changing my minimed 722 pump
Monica Zimmerman
Published 10/16/2012

- Said she needed to flip it upside but then turned it sideways and removed the insulin from the transfer guard and then removed reservoir from transfer guard.

Reservoir on top:

https://www.youtube.com/watch?v=h8yrPRHVFGU
Infusion Set and Reservoir Change (Medtronic Sure-T)
melissazimmermann
Published 2/10/2016

- Put insulin vial on table upside down and removed reservoir from transfer guard first. Did it like the original IFU. She also explained why she did it right and the need to ensure top of reservoir is dry before connecting pcap.

https://www.youtube.com/watch?v=kIg5Xt36Wh4
How to change out your infusion set for MiniMed 722
Natalie Lefthand
Pulished 10/2/2010

- Holds unit with reservoir on top and insulin on bottom. Pulls off reservoir first.
- However, he is child and he handed the unit to his mother to check for air bubbles. She handed it back to him and he just popped it off the way he was given it (no effort to ensure vial was below reservoir)

https://www.youtube.com/watch?v=agF5YxJsvAM
How to change your infusion set for your Medtronic pump (the poor and unsafe way lol...)
Albert Irby
Published 2/19/2012

- Reservoir upside down on top, insulin vial upside right. Was very careful in removing reservoir from transfer guard which was still connected to the insulin vial.

https://www.youtube.com/watch?v=1hR_2gMJSg4
How To Change an Insulin Pump Site

MsBHS2014's channel
Published 12/17/2011

- Turned unit over with reservoir on top. Removed reservoir from transfer guard first.